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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/770,091	02/02/2004	Richard A. Hamer	FLI-14402/03	9264
25006	7590	09/21/2006	EXAMINER	
GIFFORD, KRASS, GROH, SPRINKLE & CITKOWSKI, P.C			WARE, DEBORAH K	
PO BOX 7021			ART UNIT	
TROY, MI 48007-7021			PAPER NUMBER	

1651

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/770,091

Applicant(s)

HAMER ET AL.

Examiner

Deborah K. Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1 and 3-10 are presented for reconsideration on the merits.

#### ***Response to Amendment***

The amendment filed June 21, 2006 has been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1 and 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over previously cited Carpenter et al (US 5356803) in view of newly cited Mao et al (US 6153212) cited on enclosed PTO-1449 Form.

Claims are drawn to a method for treating a microbe mediated dermatological condition in an organism, comprising treating an affected tissue of said organism with an agent that is capable of disrupting a microbial biofilm. Galactosidase can be the agent and further the treatment can include a step comprising treating with an antimicrobial compound.

Carpenter et al teach a method for treating a microbe mediated dermatological condition in an organism, comprising treating an affected tissue of said organism with an agent that is capable of disrupting a microbial biofilm. Surfaces to be treated include biofilms, note col. 14, line 4. At col. 10, line 65, galactosidase is disclosed as a critical treatment agent. The method is disclosed to be practiced on a living organism, note col. 10, lines 27-30. The composition of the disclosed method includes anti-acne compositions and surfaces to be treated include skin, note col. 19, lines 26 and 45. The galatocidases can be used alone and/or in combination with a different component comprising antimicrobial compounds, note col. 3, lines 49-53.

Mao et al teach guaifenesin as a biologically active substance, see column 13, line 2.

The claims differ from Carpenter et al since guaifenesin is not disclosed.

It would have been obvious to one of ordinary skill in the art to incorporate into the disclosure of Carpenter et al the guaifenesin as disclosed by Mao et al in order to

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provide for a method for treating a microbe mediated dermatological condition because the guaifenesin is a biologically active substance. Carpenter et al teach each of claim limitations set forth in claims 5-9. The claims are prima facie obvious over the cited prior art.

Claims 1 and 9 are rejected under 35 U.S.C. 103 as being obvious over Kramer et al (US 5,320,805), previously cited in view of newly cited Mao et al on enclosed PTO-892 Form.

Claims are discussed above and are further drawn to an agent being selected from not only peroxide radicals, but can be sonic waves.

Kramer et al teach a method for treating an affected tissue with an agent such as sonic waves and/or peroxide radicals, note col. 7, lines 35-36 and col. 13, lines 40-42, wherein biofilms are disrupted as a result of destroying or killing off the microbes making up the biofilms. Skin is treatable as noted at col: 2, line 23.

Mao et al is discussed above.

The claims differ from Mao et al in that guaifenesin is not disclosed.

It would have been obvious to one of ordinary skill in the art to incorporate into the disclosure of Kramer et al the guaifenesin as disclosed by Mao et al in order to provide for a method for treating a microbe mediated dermatological condition because the guaifenesin is a biologically active substance. Kramer et al teach each of claim limitations set forth, for example, skin. The claims are prima facie obvious over the cited prior art.

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Claims 1 and 4 are rejected under 35 U.S.C. 103 as being obvious over Crisp et al (US 6522918), previously cited in view of newly cited Mao et al cited on enclosed PTO-892 Form.

Claims are discussed above and are further drawn to an agent comprising an electrical field.

Crisp et al teach treating skin on the body with an electrical field to promote healing action for medicinal and hygienic purposes and that electrical fields can exert a microbiocidal effect on tissues such as biofilms and hence disrupt them, note col. 1, lines 15-26.

Mao et al is discussed above.

The claims differ from Mao et al in that guaifenesin is not disclosed.

It would have been obvious to one of ordinary skill in the art to incorporate into the disclosure of Crisp et al the guaifenesin as disclosed by Mao et al in order to provide for a method for treating a microbe mediated dermatological condition because the guaifenesin is a biologically active substance. Crisp et al teach each of claim limitations set forth, for example, electric field. The claims are prima facie obvious over the cited prior art.

Claims 1 and 5-10 are rejected under 35 U.S.C. 103 as obvious over Burrell et al (US 6939568), previously cited in view of newly cited Mao et al on enclosed PTO-892 Form.

Claims are discussed above and further are drawn to treating tissue comprising nail tissue and a dermatological condition comprising dermatophytoma.

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Burrell et al teach a method for treating a microbe mediated dermatological condition in an organism, such as dermatophytoma of nail tissue, note col. 3, lines 46-68, comprising treating an affected nail tissue of said organism with an agent, such as peroxide radicals (i.e. benzoyl peroxide), note col. 5, line 34. Acne of the skin can also be treated, note col. 4, line 14. Further, another antimicrobial metals are used as well, note the abstract, lines 1-2.

Mao et al is discussed above.

The claims differ from Mao et al in that guaifenesin is not disclosed.

It would have been obvious to one of ordinary skill in the art to incorporate into the disclosure of Burrell et al the guaifenesin as disclosed by Mao et al in order to provide for a method for treating a microbe mediated dermatological condition because the guaifenesin is a biologically active substance. Burrell et al teach each of claim limitations set forth, for example, skin. The claims are prima facie obvious over the cited prior art.

The microbial biofilm is inherent to the cited disclosure because the inflammatory dermatological conditions of the skin are taught to be caused by microbial colonies of which are well known in the art to be comprised by biofilms. It would have been obvious to one of ordinary skill in the art to disrupt a microbial biofilm to treat the dermatological condition as disclosed by Burrell et al.

One of skill would have been motivated by the teachings therein for treating a microbe mediated dermatological condition in an organism comprising treating an affected tissue of the organism with an agent, like peroxide radicals, to disrupt bacterial growth whether in the form of an infection or in a microbial biofilm. Clearly one of skill

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would have expected successful results. To add an antimicrobial compound of Mao et al, simultaneously or after the treating agent is clearly an obvious modification of the cited prior art. Acne is clearly disclosed to be treatable as is dermatophytoma of the skin and nail tissue. The claims are in the alternative rendered prima facie obvious over the cited prior art.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carpenter et al (US 5356803), previously cited above in view of previously cited Burrell et al (US 6939568), cited above as well, both in view of newly cited Mao et al.

Claim 10 is drawn to the method comprising affected tissue that is nail tissue and a condition comprising dermatophytoma.

Carpenter et al and Burrell et al and Mao et al are all discussed above.

The claim differs from Carpenter et al in that nail tissue and dermatophytoma are not disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of Carpenter et al and Burrell et al and Mao et al to provide for a method for treating dermatophytoma wherein the affected area is nail tissue with the disruption of a biofilm as disclosed by the cited prior art combination.

To disrupt the biofilm disclosed by Carpenter et al by treating nail tissue with guaifenesin of Mao et al would have been clearly expected to successfully treat dermatophytoma because the prior art recognizes that the agents disclosed by Carpenter et al and Burrell et al have been successful for treating a microbe mediated



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dermatological condition in an organism and guaifenesin is a biologically active agent.

Thus, one of skill would have expected successful results. In the absence of persuasive evidence to the contrary the claims are rendered prima facie obvious over the cited prior art.

***Response to Arguments***

Applicant's arguments filed June 21, 2006, have been fully considered but they are not persuasive. The arguments that guaifenesin is not disclosed are noted but not persuasive since Mao et al newly applied teaches the compound to be biologically active.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

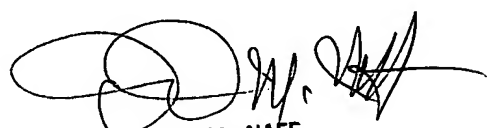
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Deborah K. Ware  
August 29, 2006

  
DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 128/651